Exhibit 6

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Design and Surface Characteristics of 13 Commercially Available Oral Implant Systems

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Thirteen commercially available oral implant systems were investigated with respect to design and surface topography. The implants were divided into four groups, depending on their different surface materials and treatments. Surface topography was measured with a measurement system for noncontact surface profilometry using confocal scanning microscopy. Results indicated that design, as well as surface topography, varied considerably between the different implant systems.
(Int J Oral Maxillofac Implants 1993;8:622–633.)

Key words: design, optical profilometry, oral implants, surface topography

Design and surface structure are two of six factors proposed by Albrektsson et al[1] to influence bone apposition to an implant. The importance of different designs has been investigated by, among others, Carlsson et al[2] and Maniatopoulos et al.[3] Surface quality can be considered a combination of all properties of a surface, ie, physical, chemical, mechanical, and surface structure. Different aspects of surface quality have been studied by Baier et al,[4] Kasemo and Lausmaa,[5] and Chehroudi et al.[6] Baier et al[4] were the first to point out the importance of high surface energy for improved implant acceptance, at least with respect to soft tissue attachment. Recently, Binon et al[7] investigated the chemical composition of surfaces from four dental implant systems. They found varying degrees of contamination in and near the surface for each implant. The implants treated with radiofrequency glow discharge exhibited the cleanest surfaces.

In several studies, rough surfaces have been found to have a better fixation in bone than smooth surfaces.[8–10] To be able to investigate and characterize an optimal surface structure, there is need for an appropriate method. Previously, such a method has been lacking, especially in the case of screw-shaped implants. In this study, a newly developed method for surface roughness characterization, described in detail by Wennerberg et al,[11] has been used. The system, TopScan 3D (Heidelberg Instruments, Heidelberg, Germany), is an optical profiler for three-dimensional measurements in the µm range. The purpose of this study was to briefly describe the design and characterize, in qualitative as well as quantitative detail, the surface structure of 13 different commercially available oral implant systems.

Materials and Methods

Surface topography was described for 13 oral endosseous implant systems, all commercially available from different manufacturers. The implants (eight cylindrical and five screw-shaped) were divided into four groups with respect to their different surface materials.

Group A. Hydroxyapatite (HA)-coated implants; this group consisted of six cylindrical systems.

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Group B. Titanium plasma-sprayed implant; one cylindrical system was in this group.

Group C. Titanium alloy implants; this group included one cylindrical and two screw-shaped implants.

Group D. Commercially pure titanium implants; this group consisted of three screw-shaped implants.

Some of the implants had special design variations. For example, Core-Vent (Dentsply Implant Division, Encino, CA) is a cylindrical implant with some threads toward the top. Other cylindrical implants are designed with longitudinal furrows.

Photographs were taken to provide a visual description of the appearance of the different implant systems. A Nikon Measurescope 10 (Nikon, Tokyo, Japan) equipped with a digital counter was used to measure the diameter of the implants. Core diameters and pitch heights were also measured for three of the cylindrical and all of the screw-shaped specimens. These measurements were performed at 3 different sites on every implant, and the mean value was calculated. Furthermore, to calculate the flange angles, profile drawings of every screw-shaped implant and of three cylindrical systems were made.

Surface topographic description was performed using the Top Scan 3D system, which is optical equipment specially developed for surface roughness characterization of arbitrarily shaped objects. A small laser spot is used as an optical stylus. The system employs the method of confocal laser scanning microscopy, probing the surface specimens by simultaneously measuring the reflected laser light and the coordinate position (xyz) of the laser spot. This gives a high depth resolution (20 nm), since only light reflected from the focal plane reaches the point detector for further computer evaluation.[12] To exclude form and waviness from the roughness, a Gaussian filter[13] was used.

The measured area in all cases was 250 × 250 µm. Because of the strong curvature of the objects, it was not useful to measure a larger area. The depth was up to 108 µm. The number of measured areas differed, depending on implant design. The cylindrical specimens were measured on the bottom, midsection, and top of the implants, with scanning direction both perpendicular to and along the long axis of the implant. The object was then turned around and similar measurements were performed on the other side. Thus a total of 12 measurements were made for every cylinder. For cylinders with longitudinal furrows, an excess number of measurements were obtained. In those cases the surface structure was measured in the furrow, at the bottom, midsection, and top of the cylinder, with the scanning direction as described above. This approach involved an additional 12 measurements.

The screw-shaped implants were measured on the top, midsection, and bottom, and for each site one flange, one thread-top, and one thread-valley were measured. Scanning was performed in the x as well as in y direction. The screw was then turned around and measured the same way on the other side. This procedure provided a total of 36 measurements for each screw. For one cylinder design, the Micro-Vent (Dentsply Implant Division), which had circumferential grooves and longitudinal furrows, additional measurements were made in a manner similar to that with screws and with the cylinders that had furrows. A total of 48 measurements were made on this specimen. With the Core-Vent implant design (cylinder with some threads), a combination of measurement routines for screws and cylinders was used. A total of 46 measurements were performed on this implant.

Visual images from the TopScan program were produced for each implant. For the numerical description, the following surface roughness parameters were used:

R_a – the average absolute deviation from the mean line over 1 sampling length, measured in µm.

R_q – the root-mean-square (rms) deviation from the profile mean over 1 sampling length, measured in µm and corresponding to R_a.

R_t – the maximum peak-to-valley height of the profile in the assessment length, measured in µm.

R_{sk} – skewness, the symmetry of the profile about the mean line. This describes the shape of the height distribution and is not specified in units. A value of 0 indicates that there are as many peaks as valleys.

R_{ku} – kurtosis, a measure of the sharpness of the surface profile not specified in units. A Gaussian height distribution has a value of 3. If kurtosis is > 3, there are relatively many high peaks and low valleys.

Δ_q – the rms slope of the profile throughout the assessment length, measured in degrees.

λ_q – average wavelength, a measure of the spacing between local peaks and valleys, taking into account their relative amplitudes and individual spatial frequencies, measured in µm.

Results

Even for the naked eye, differences in surface structure were obvious between the four groups of implants. Without appropriate measurement equipment, it is more difficult to separate the different specimens in the same group with respect to surface roughness. The TopScan 3D system has been used to produce visual images and numerical analyses for

Table 1 A Comparison of 13 Different Oral Implant Systems With Respect to 7 Different Surface Roughness Parameters

	R_a	R_t	R_q	R_{sk}	R_{ku}	Δ_q	λ_q
Group A							
Osteobond, HA							
Mean value	2.94	32.51	3.83	−0.21	4.05	56.53	24.3
SD	0.52	6.42	0.65	0.34	0.76	5.4	2.5
IMZ, HA							
Mean value	2.76	38.41	3.62	−0.2	4.39	56.67	22.92
SD	0.31	4.8	0.44	0.36	1.16	3.21	1.74
Micro-Vent, HA							
Mean value	1.89	22.08	2.43	−0.09	4.07	45.79	19.08
SD	0.28	4.7	0.39	0.28	0.99	4.88	1.84
Bio-Vent, HA							
Mean value	1.76	20.68	2.27	0.15	4.38	44.65	18.32
SD	0.23	9.24	0.36	0.39	4.27	4.86	1.56
Impla-Med, HA							
Mean value	1.69	20.09	2.18	−0.17	3.94	46.27	16.96
SD	0.17	5.34	0.25	0.32	1.05	2.48	1.34
Calcitek, HA							
Mean value	1.59	16.26	2.02	−0.06	3.49	46.72	15.43
SD	0.37	2.9	0.47	0.31	0.37	3.30	2.39
Group B							
IMZ, Ti							
Mean value	1.82	25.9	2.44	−0.44	5.36	51.96	16.8
SD	0.43	4.92	0.55	0.19	1.08	5.44	2.1
Group C							
Core-Vent, ti-alloy							
Mean value	1.21	18.14	1.65	−0.49	6.38	44.20	13.09
SD	0.49	5.37	0.64	0.49	2.54	10.08	2.87
Screw-Vent, ti-alloy							
Mean value	0.56	10.21	0.79	−0.35	7.56	27.51	10.10
SD	0.23	6.02	0.35	0.67	4.97	8.42	1.78
3I Miniplant, Ti							
Mean value	0.41	9.53	0.61	−0.66	13.59	20.28	11.34
SD	0.17	4.39	0.26	0.93	7.66	8.73	3.24
Group D							
3I, Ti							
Mean value	0.67	15.67	1.09	−0.79	24.27	28.38	13.98
SD	0.38	12.05	0.72	2.30	73.9	15.55	4.8
Impla-Med, Ti							
Mean value	0.54	10.74	0.8	−0.61	10.3	22.39	13.18
SD	0.29	5.8	0.43	0.81	4.64	8.89	5.1
Nobelpharma, Ti							
Mean value	0.53	9.69	0.79	−0.65	10.07	23.8	12.96
SD	0.10	2.41	0.17	1.13	4.05	6.19	5.03

each of the implant systems. The presentation also included photographs and the measured (by authors) length and mean value for diameter (∅); figures for ∅ in parentheses correspond to the information written on the implant package. Finally, a profile drawing is included for the screw-shaped implants and for three of the cylindrical implants with a special design. Table 1 provides the values for seven surface roughness parameters and a comparison between the different implants. The skewness parameter was similar for all implants and in all cases, except for the Bio-Vent (Dentsply Implant Division) implant, which was slightly negative. This indicates that there were a few more valleys than there were peaks, but according to Thomas,[14] skewness values of less than ±1 are probably not significant. All other parameters used differed considerably from implant to implant.

Group A. The HA-coated implants included six cylindrical implants and these had the highest surface roughness. This group was very unhomogeneous with respect to design and surface structure. Osteobond (Stryker Dental Implants, Kalamazoo, MI) was the roughest of all examined implants. The IMZ (Interpore International, Irvine, CA) HA-coated implant had roughness figures similar to those of the

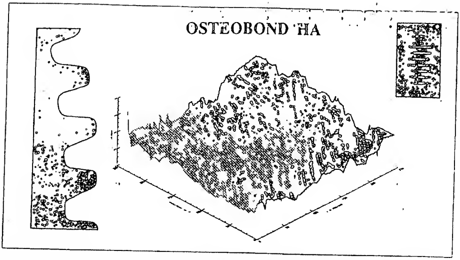

Fig 1 Osteobond, an HA-coated cylinder with six circumferential deep grooves, the roughest of all implants in present study.

Osteobond. These two implant designs differed markedly from the others. The Calcitek (SULZER-medica, Carlsbad, CA) HA-coated design had the smoothest surface, with a dense texture but not as high peaks and low valleys as the Osteobond. Implants included in this group were the following.

1. *Osteobond* root implant is an HA-coated cylinder with a conical head and a slight cone angle at the body, having six circumferential deep grooves with four longitudinal furrows in the "apical" part. The specimen measured was 8 mm in length. Diameter (Ø) at the central part of the implant was 4 mm (4 mm) and the core diameter was 2.9 mm. The pitch height was 1 mm. This implant did not have a uniform flange angle and every groove had a different value, as is obvious from Fig 1. The Osteobond implant had the roughest mean value R_a, 2.94 μm, and the second highest value for R_t, which was 32.52 μm. The λ_q was 24.3 μm, the highest value of this study, indicating that this implant design had the most open surface structure of all specimens examined.
2. *IMZ* is an HA-coated cylinder, with a length of 13 mm and Ø = 3.3 mm (3.3 mm) (Fig 2). This implant had the second highest mean value for surface roughness, R_a = 2.76 μm, and the highest value measured from the highest top to the lowest valley; R_t = 38.41 μm. The value for λ_q was 22.92 μm, indicating a rather open surface structure compared to the other implants included in this study.
3. *Micro-Vent* is an HA-coated cylinder with a particular design and varying diameter. This implant has two longitudinal furrows, a length of 16 mm, Ø = 3.28 mm (3.25 mm), core diameter of 2.68 mm and pitch height of 1.0 mm, maximum radial diameter of 0.32 mm, and minimum radial diameter of 0.25 mm (Fig 3). This implant exhibited a rougher and more open surface structure than did the Impla-Med (Impla-Med, Sunrise, FL) and Calcitek implants. R_a value for Micro-Vent was 1.89 μm, R_t = 22.08 μm, and λ_q = 19.08 μm.
4. *Bio-Vent* is an HA-coated cylinder with three longitudinal furrows, length = 13 mm and Ø = 3.6 mm (3.5 mm) (Fig 4). The R_a value was 1.76 μm, R_t = 20.68 μm, and λ_q = 18.32 μm.
5. *Impla-Med* is an HA-coated cylindrical implant with length = 13 mm and Ø = 3.3 mm (3.3 mm) (Fig 5). Values for the surface roughness were slightly higher than those of the Calcitek. Values for R_a, R_t, and λ_q were 1.69, 20.09, and 16.96 μm, respectively.
6. *Calcitek* is an HA-coated cylinder with a length of 13 mm, Ø = 3.17 mm (3.25 mm (Fig 6). The Calcitek implant had the smoothest surface among the HA-coated implants, even though it was rough compared to the commercially pure titanium implants. Values for R_a, R_t, and λ_q were 1.59, 16.26, and 15.43 μm, respectively.

Group B. Only 1 of the 13 implants in this study had a titanium-plasma-sprayed surface.

7. *IMZ*, a titanium-plasma-sprayed implant cylinder, had length = 11 mm and Ø = 4.0 mm (4.0 mm) (Fig 7). R_a = 1.82 μm and R_t = 25.9 μm. The surface structure was more closed than the structure of the Osteobond and IMZ HA-coated im-

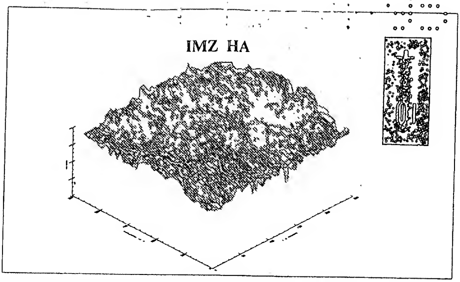

Fig 2 IMZ, an HA-coated cylinder; a very rough surface with appearance similar to that of the Osteobond implant.

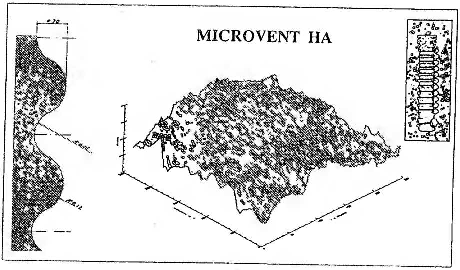

Fig 3 Micro-Vent, an HA-coated cylinder with a systematically varying diameter and two longitudinal furrows; a rough surface but smoother than the Osteobond and IMZ implants.

plants, and similar to the somewhat smoother HA-coated implants as shown by the value for λ_q, 16.8 µm.

Group C. Three implants were manufactured of titanium alloy, two screw-shaped and one cylinder. The values of the surface parameters were quite different among these three implants.

8. *Core-Vent*, a cylindrical design with some threads towards the top of the implant; length = 13 mm and Ø = 3.5 mm for the cylindrical part (3.5), 4.25 mm for the "screw-part" core diameter = 3.5 mm, pitch height = 1.0 mm, flange angle = 102 degrees, and the thread top was rounded in two steps with a radius of 0.17 mm and 0.05 mm,

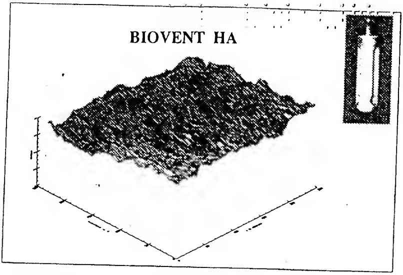

Fig 4 Bio-Vent, an HA-coated cylinder with three longitudinal furrows and a surface structure in the intermediate range of roughness compared to the other measured HA-coated implants.

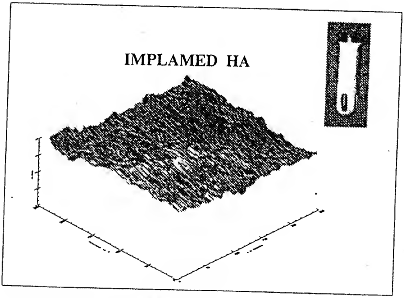

Fig 5 Impla-Med, an HA-coated cylinder. This implant had a surface structure slightly rougher than the Calcitek HA-coated implant.

respectively (Fig 8). R_a = 1.21 μm, R_t = 18.14, and λ_q = 13.09 μm. This implant was much rougher than the Screw-Vent.

9. *Screw-Vent*, a screw-shaped implant; length = 10 mm, Ø = 3.70 mm (3.75 mm), core diameter = 3.12 mm, pitch height = 0.6 mm, and flange angle = 60 degrees; the top was truncated and the bottom rounded, with a radius of 0.07 mm (Fig 9). Corresponding values for R_a, R_t, and λ_q were 0.56 μm, 10.21 μm, and 10.10 μm. The λ_q value indicates that this implant had the most closed surface structure of the specimens included

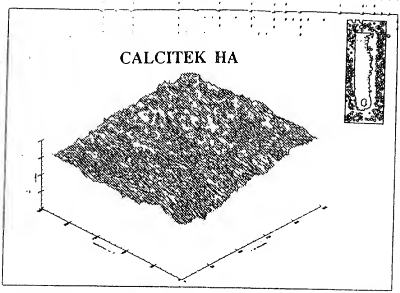

Fig 6 Calcitek, an HA-coated cylinder; the smoothest of all measured HA-coated implants

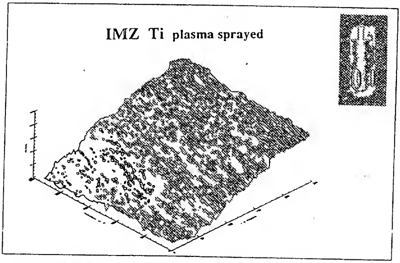

Fig 7 IMZ, a titanium plasma-sprayed cylinder. This implant exhibited a fairly rough surface structure, similar to that of the HA-coated Micro-Vent cylinder.

in this investigation. This surface structure was similar to those of the commercially-pure titanium implants.

10 *3I-MiniPlant* (3I Implant Innovations, Palm Beach, FL), a screw-shaped implant with length = 10 mm, Ø = 2.9 mm (2.9 mm), core diameter = 2.48 mm, pitch = 0.6 mm, flange angle = 60 degrees, and a truncated thread top and bottom (Fig 10). The smoothest of all implants in this study (R_a = 0.41 µm, R_t = 9.53 µm, and λ_q = 11.34 µm), it represented the second most closed surface structure of all 13 implant designs.

Group D. Three implants, all screw-shaped, were made of commercially pure titanium. As a group, these were the smoothest implants in this study, with R_a values from 0.53 to 0.67 µm. The implants in this

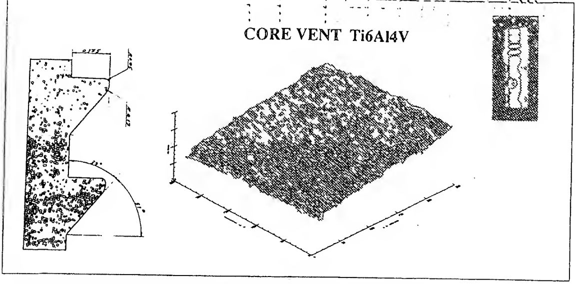

Fig 8 Core-Vent, a titanium alloy cylinder with some threads towards the top of the implant. This implant had a surface structure that was clearly separate from all other implants in the present study. Core-Vent was much smoother than the HA-coated and titanium plasma-sprayed implants and much rougher than the other two titanium alloy implants and the implants made of commercially pure titanium.

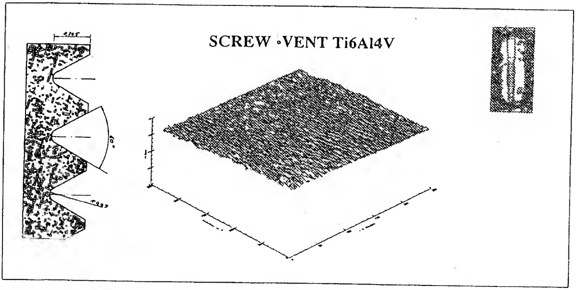

Fig 9 Screw-Vent, a titanium alloy screw with a rounded small thread bottom and a truncated thread top. This implant had a smooth surface structure similar to the commercially pure titanium screws, and a dominant direction of the surface topography perpendicular to the long axis of the screw.

group all exhibited a similar surface pattern, with grooves perpendicular to the long axis of the screws. 11. 3I, a standard threaded implant with length = 13 mm, Ø = 3.72 mm (3.75 mm), core diameter = 3.12 mm, pitch height = 0.6 mm, and flange angle = 60 degrees. The thread top is truncated and the bottom rounded off with a radius of 0.05 mm (Fig 11). The roughest im-

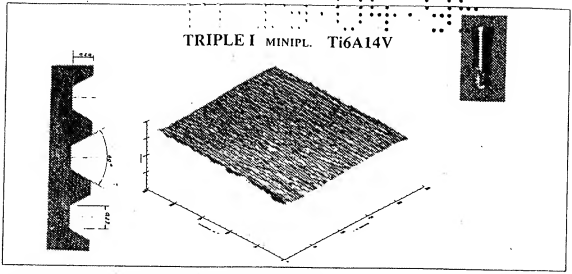

Fig 10 3I Miniplant, a titanium alloy screw with a truncated thread bottom and thread top; the smoothest of all measured implants of the present study, with a dominant direction of the surface pattern.

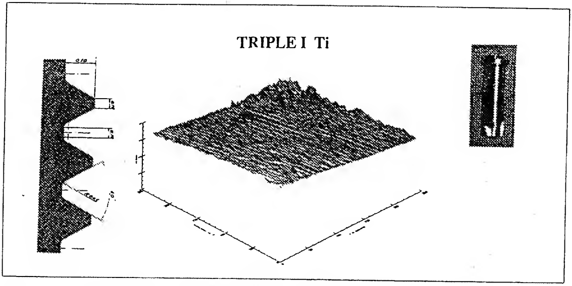

Fig 11 3I standard threaded implant, a commercially pure titanium screw with a slightly rounded thread bottom and with a truncated thread top. A smooth surface but the roughest of the three commercially pure titanium screws, with the same direction of the surface pattern as the Screw-Vent, 3I Miniplant, and the other commercially pure titanium screws.

plant among the commercially pure titanium group, with R_a = 0.67 μm, R_t = 15.67 μm, and λ_q = 13.98 μm. The $R_{\Delta q}$ of 24.3° was much higher than for any of the implants in this study, and is explained by some very deep scratches in one flange of the measured specimen.

12. *Impla-Med*, a standard screw implant with length = 13 mm, Ø = 3.70 mm (3.75 mm), core diameter = 3.05 mm, pitch height = 0.6 mm, and flange angle = 60 degrees. The thread top and bottom were truncated, not rounded (Fig 12). R_a = 0.54 μm, R_t = 10.74 μm, and λ_q = 13.18 μm.

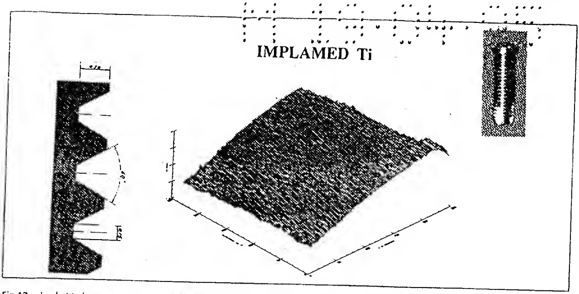

Fig 12 Impla-Med, a commercially pure titanium screw with a truncated thread bottom and thread top; a smooth surface and values for the surface structure similar to the Screw-Vent titanium alloy implant.

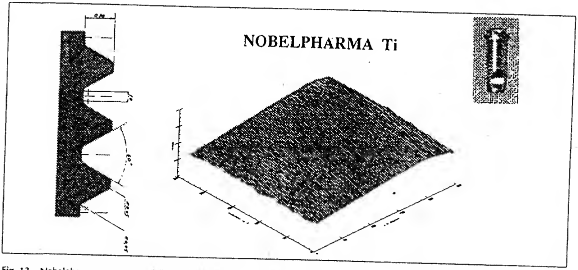

Fig 13 Nobelpharma, a commercially pure titanium screw with a rounded thread bottom and thread top: the smoothest of the commercially pure titanium screws

13. *Nobelpharma* (Nobelpharma AB, Göteborg, Sweden), a self-threaded implant with length = 10 mm, Ø = 3.71 mm (3.75 mm), core diameter = 3.09 mm, pitch height = 0.6 mm, and flange angle = 60 degrees. It has a rounded thread top and bottom, with a radius of 0.05 mm (Fig 13). R_a = 0.53 µm, R_t = 9.69 µm, and λ_q = 12.96 µm.

Discussion

Although several studies have suggested that a rough surface is preferable for bone apposition, negative consequences of substantial surface irregularity cannot be disregarded. When increasing surface area, there is simultaneously a risk for increased ion release, as indicated by Osborn et al.[13] These authors

demonstrated no less than 1,600 ppm titanium in haversian canals adjacent to IMZ implants, one of the roughest designs of the present study. Furthermore, primary stability could be negatively influenced by an increase in surface roughness, which could counteract the stabilization of the implant, known to be essential for implant fixation.[16] The "ideal roughness" of an implant with respect to long-term function remains to be described. Not only roughness as such, but the kind of roughness and local dimensions of the rough surface have been suggested as important for bone apposition to an implant. Wilke et al[17] found when comparing six groups of different surface structures that the highest required removal torque was needed for the acid-treated screws with a rough surface. They discussed the importance of this chemical modification of a rough surface. In an in vitro study, Bowers et al[18] found significantly higher levels of attachment of osteoblast-like cells to a rough sandblasted surface with irregular morphologies when compared to smooth and regular surfaces.

In view of these studies, we have included not only height-descriptive surface roughness parameters but also space-descriptive parameters in our study. Which of the surface roughness parameters that will best describe and predict the outcome of an implant is not known. Therefore, as many as seven different parameters have been used. The Δ_q and λ_q describe the openness and closeness of the whole surface; whereas the five other parameters used are height descriptors. Applications and disadvantages have been well clarified by Thomas.[14] Both in two- and three-dimensional measurements of surface roughness, no useful deduction can be made if waviness and errors of form are excluded.[19] The short wavelengths of the profile define the roughness, while the longer ones define waviness and form. In the two-dimensional situation, the cutoff length works as a filter, and well-established international standards exist. In the three-dimensional situation, no standards exist, and cutoff length becomes a cutoff area, which may vary in size and shape. This will influence the parameter values, and specification of filter choice and filter size is essential if measurements with one type of equipment are to be compared with those made with another. In the future, there will be a need for some kind of agreement about evaluation of different measurements made by different equipment.

Results from this investigation showed that surface structure varied among the different implants. The six HA-coated implants in Group A exhibited great variation. Two, the Osteobond and IMZ implants, were most rough, as evidenced in all applied surface roughness parameters. The Bio-Vent, Impla-Med, and Calcitek designs showed similar roughness measures, but these implants were much smoother than the Osteobond and the IMZ. The great variance in surface topography among the HA-coated specimens is best explained by differences in the type of HA coating. The three titanium-alloy implants also exhibited a great difference in surface structure. Core-Vent had a considerably rougher surface than the Screw-Vent and the 3I Miniplant, the latter two being similar to the commercially pure titanium group. The three screws made of commercially pure titanium showed a more homogeneous surface structure when compared to the other groups. The small differences that exist in this group may be explained by different manufacturing protocols and varying sharpness of the cutting tools. The implant system having the most optimal surface is not possible to determine from this investigation. However, with the surface-analyzing method used, we are now able to separate implants with respect to surface topography, even for implants that appear similar to the naked eye.

Summary

The results from this investigation show that 13 different implants varied considerably in surface topography, not only among the different groups, ie, implants manufactured with the same kind of material, but also among different samples in the same group. Only one implant from each system was investigated in this study. One must be concerned about the variability which exists among such specimens, and thus whether or not the study results can be generalized to any larger population. This factor could be regarded negatively, but with the high number of measurements performed, we think reliable mean values for the different surface roughness parameters have been produced. However, even such relatively small differences that exist in surface roughness among implants in the commercially pure titanium group, such as the 3I standard screw and the Nobelpharma, could well result in differences in tissue responses. There is a great need for further studies in this area. To automatically regard different implant systems, obviously varying with respect to design and surface roughness, as capable of producing the same clinical results is without justification.

Acknowledgments

The authors gratefully acknowledge grants received from the Swedish Medical Research Council, Sylvans' Foundation, the Greta and Einar Asker Foundation, the Hjalmar Svensson Re-

search Foundation, the Anna Ahrenberg Foundation, the Wilhelm and Martina Lundgren Science Foundation, Swedish Dental Society, and the Swedish Society for Medical Research (Albert Hellström Foundation).

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Résumé

Caractéristiques de conception et surface de 13 systèmes d'implants actuellement disponibles sur le marché

Treize systèmes d'implants actuellement disponibles sur le marché furent évalués du point de vue de leur conception et topographie de surface. Les implants furent divisés en quatre groupes, en fonction de leur matériau de surface et de leur traitement respectifs. La topographie de surface fut mesurée à l'aide d'un système de mesure en vue d'une profilométrie de surface sans contact utilisant la microscopie à balayage confocale. Les résultats indiquent que la conception et la topographie de surface varient considérablement d'implant à implant.

Zusammenfassung

Design und Oberflächenbeschaffenheit von 13 kommerziell erhältlichen Implantatsystemen

13 kommerziell erhältliche Implantatsysteme wurden hinsichtlich Design und Oberflächenbeschaffenheit untersucht. Die Implantate wurden in Abhängigkeit von ihrem Oberflächenmaterial und ihrer Oberflächenbehandlung in 4 Gruppen eingeteilt. Die Oberflächentopography wurde mit Hilfe eines konfokalen Scannermikroskops zur profilometrischen Oberflächenmessung bestimmt. Die Ergebnisse deuten an, dass sowohl das Design als auch die Oberflächentopography zwischen den verschiedenen Implantatsystemen beträchtlich variiert.

Resumen

Diseño y características de la superficie de trece sistemas de implantes orales disponibles comercialmente

Trece sistemas de implantes orales disponibles comercialmente fueron evaluados con respecto al diseño y a la topografía de su superficie. Los implantes fueron divididos en 4 grupos, dependiendo de los diferentes materiales de su superficie y de los tratamientos de la misma. Para medir la topografía superficial se uso un sistema que mide el perfil superficial sin contacto, utilizando microscopia electrónica de barrido confocal. Los resultados indican que tanto el diseño como la topografía de la superficie variaron considerablemente entre los diferentes sistemas de implantes.